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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,544	04/01/2004	Kevin D. Kreutter	3DP-0548	1002

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EXAMINER	
OH, TAYLOR V	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 10/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/816,544	KREUTTER ET AL.	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-71* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

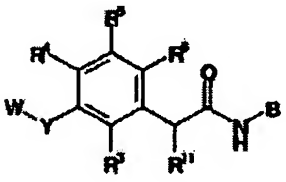
Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8.11/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restriction

I. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6,8-9,13-35, and 64-71 drawn to compounds of formula (*1*) with non-heterocyclic substituents and their pharmaceutical composition as shown the formula (*1*) below:



W is R^1 or $R^1S(O_2)$;

R^1 is R^2 is

wherein R^2, phenyl, naphthyl, or biphenyl,

Y is -NH- or O;

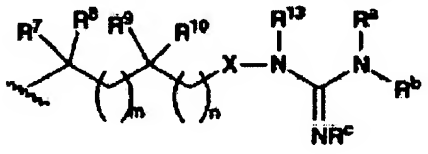
R^3 is hydrogen,halogen or OH;

R^4 and R^5 are independently hydrogen, halogen, alkyl, alkenyl, alkynyl, hydroxy, alkoxy, haloalkyl, haloalkoxy, hydroxyalkyl, cyano, nitro, $-CO_2R^x$, $-CH_2OR^x$ or $-OR^x$, where R^x, in each instance, is independently one of hydrogen or C_{1-6} alkyl;

R^6 is cyano or acetylenyl;

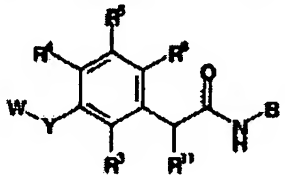
R^{11} is hydrogen, halogen or alkyl;

B is selected from the group consisting of:



classified in class 564, subclass 162.

II. Claims 1-35 and 64-71, drawn to compounds of formula (*I*) of heterocyclic substituents, and their pharmaceutical composition:



wherein

W is R^1 or $R^1S(O_2)$;

R^1 is

R^2, $(R^2)_2CH(CH_2)_r$, $(R^2)_2$ can also form a ring with a 5- to 7-membered mono- or bicyclic heterocyclic ring , $(R^2)_2CF(CH_2)_r$, $(R^2)_2$ can also form a ring with a 5- to 7-membered mono- or bicyclic heterocyclic ring

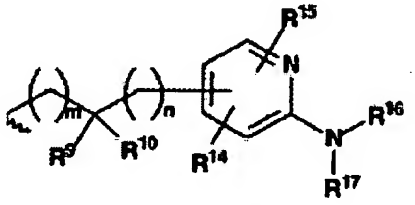
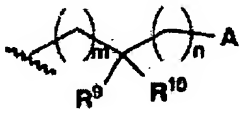
Y is -NH- or O;

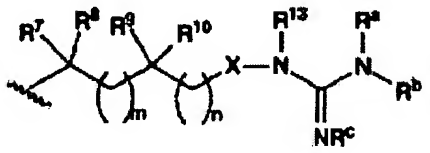
R^3 is hydrogen,halogen or OH;

R^4 and R^5 are independently hydrogen, halogen, alkyl, alkenyl, alkynyl, hydroxy, alkoxy, haloalkyl, haloalkoxy, hydroxyalkyl, cyano, nitro, $-CO_2R^x$, $-CH_2OR^x$ or $-OR^x$, where R^x, in each instance, is independently one of hydrogen or C_{1-6} alkyl;

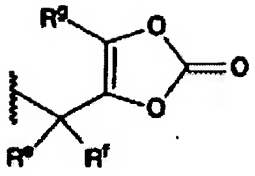
R^6 is cyano or acetylenyl;

R^{11} is hydrogen, halogen or alkyl;

B is selected from the group consisting of  or 



, wherein



R^a, R^b and R^c are $-CO_2R^w$, R^w is

, classified in class 514, subclass 227.5; 546, subclasses 93, 152; class 548, subclasses 200 and 250; class 549, subclass 229 .

III. Claims 36-44, drawn to a method of inhibiting or treating aberrant proteolysis, thrombosis, ischemic ,stroke restenosis or inflammation in a mammal using compounds of formula (*1*) with non-heterocyclic substituents classified in class 564, subclass 162.

IV. Claims 36-44, drawn to a method of inhibiting or treating aberrant proteolysis, thrombosis, ischemic ,stroke restenosis or inflammation in a mammal using compounds of formula (*1*) with heterocyclic substituents , classified in class 514, subclass 227.5; 546, subclasses 93, 152; class 548, subclasses 200 and 250; class 549, subclass 229 .

V. Claims 45-51, drawn to a medical device for use in blood collection comprising compounds of formula (*1*) with non-heterocyclic substituents classified in class 604, subclass 187.

VI. Claims 45-51, drawn to a medical device for use in blood collection comprising compounds of formula (*1*) with heterocyclic substituents classified in class 604, subclass 187.

VII. Claims 52-63, drawn to a method of inhibiting the action of a proteolytic enzyme using compounds of formula (*1*) with non-heterocyclic substituents , classified in class 435, subclasses 13, 213, 214, and 218.

VIII. Claims 52-63, drawn to a method of inhibiting the action of a proteolytic enzyme using compounds of formula (*1*) with heterocyclic substituents , classified in class 435, subclasses 13, 213, 214, and 218.

1. **The inventions are distinct, each from the other because of the following reasons: Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).**

In the instant case there are two different inventions I and II. The invention I is related to compounds of formula (*1*) of non-heterocyclic substituents, **whereas the invention II is related to** compounds of formula (*1*) of heterocyclic substituents with the side chain groups of the heterocyclic compounds contain different kinds of heterocycles, such as pyridy, pyridyl-n-oxie , quinolinyl , 1,3-xoazole, quinolinyl-n-oxide, thiazol , tetrazoly compounds.
They have different structures and different functional groups in the ring, thereby exhibiting a chemically different activity respectively. Furthermore, they are classified in different classes and subclasses; therefore, it is a burden for the examiner to search those broad classes and

subclasses. In addition, each invention has a different use and effect due to unrelated substituents attached to the core of the compounds.

If the applicants elect the invention I, the invention I is further subjected to the election species due to a plurality of disclosed patentably distinct species comprising compounds of formula (*I*) as shown in examples 2 and 11-13.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the compounds of formula(*I*) in the invention are generic. Applicants are advised to elect one species among the examples in the specification.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. **In the instant case there are two different inventions II and III. The invention II is related to** compounds of formula (*1*) of heterocyclic substituents, **whereas the invention III is related to** a method of inhibiting or treating aberrant proteolysis, thrombosis, ischemic ,stroke restenosis or inflammation in a mammal using compounds of formula (*1*) with non-heterocyclic substituents. They have different structures and different functional groups in the ring, thereby exhibiting a chemically different activity respectively for applying each of them to the method of inhibiting or treating aberrant proteolysis, thrombosis, ischemic ,stroke restenosis or inflammation in a mammal . In addition, each invention has a different use and effect due to unrelated substituents attached to the core of the compounds.

3. **In the instant case there are two different inventions III and IV. The invention III is related to** a method of inhibiting or treating aberrant proteolysis, thrombosis, ischemic ,stroke restenosis or inflammation in a mammal using compounds of formula (*1*) with non-heterocyclic substituents, **whereas the invention IV is related to** a method of inhibiting or treating aberrant proteolysis, thrombosis, ischemic ,stroke restenosis or inflammation in a mammal using compounds of formula (*1*) with heterocyclic substituents,. They have different structures and different functional groups in the ring, thereby exhibiting a chemically different activity respectively for applying each of them to the method of inhibiting or treating aberrant proteolysis, thrombosis, ischemic ,stroke restenosis or inflammation in a mammal . Therefore, they are unrelated to each other.

4. **In the instant case there are two different inventions IV and V. The invention IV is related to** a method of inhibiting or treating aberrant proteolysis, thrombosis,

ischemic ,stroke restenosis or inflammation in a mammal using compounds of formula (*1*) with heterocyclic substituents, **whereas the invention V is related to** a medical device for use in blood collection comprising compounds of formula (*1*) with non-heterocyclic substituents.
. They have each a different mode of operation and different effects since the invention of the medical device is different from that of the method of inhibiting or treating aberrant proteolysis. Therefore, they are unrelated to each other.

5. **In the instant case there are two different inventions V and VI. The the invention V is related to** the medical device for use in blood collection comprising compounds of formula (*1*) with non-heterocyclic substituents, whereas the **invention VI is related to** the medical device for use in blood collection comprising compounds of formula (*1*) with heterocyclic substituents. They have different structures and different functional groups in the ring, thereby exhibiting a chemically different activity respectively for applying each of them to the medical device for use in blood collection. Therefore, they are unrelated to each other.

6. **In the instant case there are two different inventions VI and VII. The invention VI is related to** the medical device for use in blood collection comprising compounds of formula (*1*) with heterocyclic substituents, whereas **the invention VII is related to** the method of inhibiting the action of a proteolytic enzyme using compounds of formula (*1*) with non-heterocyclic substituents. They have each a different mode of operation and different effects since the invention of the medical device is different from that of the action of a proteolytic enzyme using compounds of formula (*1*) with non-heterocyclic substituents.
Therefore, they are unrelated to each other.

7. **In the instant case there are two different inventions VI and VII. The invention VII is related to** the method of inhibiting the action of a proteolytic enzyme using compounds of formula (*I*) with non-heterocyclic substituents, whereas **the invention VI is related to** the method of inhibiting the action of a proteolytic enzyme using compounds of formula (*I*) with heterocyclic substituents. They have different structures and different functional groups in the ring, thereby exhibiting a chemically different activity respectively for applying each of them to the method of inhibiting the action of a proteolytic enzyme.Therefore, they are unrelated to each other.

Furthermore, If the applicants elect the invention II, the invention II is further subjected to the election species due to a plurality of disclosed patentably distinct species comprising compounds of formula I as shown in examples shown in examples 1,3-10, and 14-20.

8. **Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.**

9. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-VIII, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Taylor Victor Oh, MSD.LAC
Primary Examiner
Art Unit : 1625

*** 9/29/06